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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,450	12/14/2001	Guy Michael Miller	346392000900	1698

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EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	20

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/020,450	Miller et al.
Examiner	**Art Unit**
Phyllis G. Spivack	1614

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *1, 2, 4, 6, 9-23, 33-38, 42-47, and 51-62* is/are allowed.

6) ☒ Claim(s) *3, 5, 7, 8, 24-32, 39-41, and 48-50* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The Notice of Allowance mailed June 17, 2003, Paper No. 18, is withdrawn.

Claims 1-62 remain under consideration.

Claims 3, 5, 7, 8, 24-32, 39-41 and 48-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 3, 5, 7, 8, 24-32, 39-41 and 48-50 recite the limitation "metabolite". There is insufficient antecedent basis for this limitation in claim 1 from which the other claims depend.

Claims 3, 5, 7, 8, 24-32, 39-41 and 48-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the administration of gamma, beta, delta tocopherols and the single metabolite gamma-CEHC to counteract ischemia-induced neuronal cell injury and cell death, does not reasonably provide enablement for any metabolite of gamma, delta or beta tocopherol in the treatment of neuronal damage associated with cerebral ischemia. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The claims are directed to a treatment or amelioration of a symptom of neuronal damage associated with a cerebral ischemic condition comprising administering a non-alpha tocopherol or a metabolite thereof. The specification provides support for countering ischemia-induced neuronal damage comprising administering gamma-, delta-, beta-tocopherol or the single metabolite gamma-CEHC.

Attention is directed to In re Wands, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to treatment of various diseases or disorders in which neuronal damage associated with cerebral ischemia occurs.

The relative skill of those in the art is generally that of a Ph.D or M.D.

Each particular ischemic disease or condition has its own specific characteristics and etiology. The broad recitation "metabolite" of a particular tocopherol is inclusive of many structurally distinct compounds that have no support in the specification for the claimed methods of use.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The breadth of the claims

The claims are very broad and inclusive of any metabolite of gamma, beta and delta tocopherol for use in various ischemic conditions.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to the administration of gamma-, beta-, and delta-tocopherol, and the one metabolite, gamma-CEHC.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which particular metabolites would be preferred for treatment of the many types of neuronal damage that are recited in the claims. The skilled artisan would expect the mechanism of action of a specific metabolite in the treatment of a particular condition to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for each agent. The instant specification sets forth no such understanding nor any criteria for extrapolating beyond the single disclosed metabolite. No

direction is provided to administer any other metabolite in addition to gamma-CEHC. Absent a reasonable *a priori* expectation of success for using a particular metabolite to treat neuronal damage associated with cerebral ischemia, one skilled in the art would have to test extensively many metabolites to discover which one is effective in treatment. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

July 7, 2003

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER